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CONFIDENTIAL

SeaSpine VBR System

510(K) SUMMARY

Pursuant to 510(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and in accordance with 21 CFR § 807.92.

Submitter Information:

SeaSpine, Inc.
Contact: Diana Smith
2302 La Mirada Drive
Vista, CA 92081-7862
Phone: 760-727-8399 Fax: 760-727-8809

Company Registration Number: 2032593

Submission Correspondent:

SeaSpine, Inc.
Contact: Diana Smith, Manager of Regulatory Affairs and Quality Assurance
2302 La Mirada Drive
Vista, CA 92081-7862
Phone: 760-727-8399 Fax: 760-727-8809

Date Summary Prepared: August 5, 2005

Classification Name: **Spinal Intervertebral Body Fixation Orthosis**
MQP (Class II) - 888.3060

Common/Usual Name: Straight Vertebral Body Replacement (VBR), Curved VBR, Round VBR, Trapezoidal VBR, and Instruments

Device Trade Name: SeaSpine VBR System

The devices used for comparison in this summary are the Alphatec Manufacturing NOVEL VBR Spinal System (K050553 and K042201), the Interpore Cross GEO VBR Spinal System (K010530, K020048, and K040168), the Quantum Vertebral Body Replacement (K050449), and Spinal Concepts Cadence and Traxis (K033517).

1. **Intended Use:** (The statements of intended use are identical.)

The intended use of the SeaSpine VBR System straight, curved, round, and trapezoidal VBRs is substantially equivalent to the intended use of the predicate devices.

The SeaSpine VBR System is intended for use in the thoracolumbar spine (T1 to L5) to replace a collapsed, diseased, damaged or unstable complete or partial vertebral

body due to tumor or trauma/fracture, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

The SeaSpine VBR System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column, even in the absence of fusion for a prolonged period. Additionally, the SeaSpine VBR System is intended for use with bone graft.

2. Description:

The SeaSpine VBR System straight, curved, round, and trapezoidal VBRs are manufactured out of PEEK OPTIMA® polymer with tantalum wires and/or beads. All VBR configurations will be offered in numerous lengths and sizes. The product is supplied "NON-STERILE" and must be sterilized prior to use.

The SeaSpine VBR System will offer a wide variety of instruments that range from paddle scrapers to inserters. These various instruments will be made primarily from stainless steel with handles made from Radel or Pomalux. These items are supplied "NON-STERILE" and must be sterilized prior to use.

3. Technological Characteristics:

The straight, curved, round, and trapezoidal VBRs and instruments in this notification are components of a new stand alone system called the SeaSpine VBR System. The devices in this submission have substantially equivalent technological characteristics to the predicate devices. The devices in this submission also underwent appropriate mechanical testing and those results were found to be substantially equivalent to those of the predicate devices. Refer to **Table 1** on the following page, entitled *Comparison Analysis*, for a summation of technological characteristics such as design, dimensional specifications, material, and testing.

4. Comparison Analysis:

The overall designs of the SeaSpine VBR System straight, curved, round, and trapezoidal VBRs are substantially equivalent to the predicate devices. See **Table 1** on the following page for a comparison of the SeaSpine VBR System straight, curved, round, and trapezoidal VBRs to the predicate devices.

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SeaSpine VBR System

Feature	SeaSpine VBR System	Alphatec NOVEL VBR Spinal System	Interpore Cross GEO VBR Spinal System	Quantum Vertebral Body Replacement	Spinal Concepts Cadence and Traxis	Substantially Equivalent
Intended Use	The intended use of the SeaSpine VBR System is as a vertebral body replacement to correct spinal disorders and provide stabilization of the spine to permit the biological process of spinal fusions to occur.	Similar	Similar	Similar	Similar	Yes
Indications for Use	•Trauma/fracture •Tumor	Similar	Similar	Similar	Similar	Yes
Design	•PEEK implants with tantalum markers •Multiple shapes	Similar	•Titanium implants •Multiple shapes	Similar	Similar	Yes
Straight VBR	Various sizes	Similar	Similar	Similar	Similar	Yes
Curved VBR	Various sizes	Similar	Similar	Similar	Similar	Yes
Round VBR	Various sizes	Similar	Similar	NA	NA	Yes
Trapezoidal VBR	Various sizes	Similar	Similar	NA	NA	Yes
Material	PEEK and Tantalum	Similar	Titanium (per ASTM F-1108)	Similar	Similar	Yes
Sterile	Non-sterile	Similar	Sterile and Non-Sterile	Similar	Similar	Yes
Mechanical Testing	Conducted according to recognized standards	Similar	Similar	Similar	Similar	Yes
Method of Sterilization	High-temperature steam	Similar	Similar	Similar	Similar	Yes

Table 1: Summary of Design Comparison

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 1 2005

Ms. Diana Smith
Manager of Regulatory Affairs & Quality Assurance
SeaSpine, Inc.
2302 La Mirada Drive
Vista, California 92081-7862

Re: K052170
Trade/Device Name: SeaSpine Vertebral Body Replacement (VBR) System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: II
Product Code: MQP
Dated: December 1, 2005
Received: December 2, 2005

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson,
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K052170

Device Name: SeaSpine VBR System

Indications for Use:

The SeaSpine VBR System is intended for use in the thoracolumbar spine (T1 to L5) to replace a collapsed, diseased, damaged or unstable complete or partial vertebral body due to tumor or trauma/fracture, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

The SeaSpine VBR System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column, even in the absence of fusion for a prolonged period. Additionally, the SeaSpine VBR System is intended for use with bone graft.

Prescription Use ___X___ AND/OR Over-The-Counter-Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE ~~DO NOT WRITE BELOW~~ THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED).

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K052170